K120884

JUL 3 2012

Section 5-

510(k) Summary

Submitter's Name & Address

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Date of Summary

The Summary was prepared 15th of March 2012.

Device Information

Trade name: PeriCam PSI
Model No: PeriCam PSI NR, PeriCam PSI HR
Type of product: Finished product
Panel: Cardiovascular

Common Name, Classification Name, Class & Classification Regulation:

Common Name	*Classification Name*	*Class*	*Classification Regulation*	*Product Code*
Blood Perfusion Imager	Cardiovascular blood flow meter	II	870.2100	DPW

Predicate Device Information

Predicate Device No 1

Trade name: PIM 3 Laser Doppler Perfusion Imager
Model No: PIM 3
510(k) No: K920844
Type of product: Finished product
Panel: Cardiovascular

Common Name, Classification Name, Class & Classification Regulation:

Common Name	*Classification Name*	*Class*	*Classification Regulation*	*Product Code*
Blood Perfusion Imager	Cardiovascular blood flowmeter	II	870.2100	DPW

Predicate Device No 2

Trade name: moorFLPI Full-Field Laser Perfusion Imager
Model No: moorFLPI Full-Field Laser Perfusion Imager
510(k) No: K063586
Type of product: Finished product
Panel: Cardiovascular

Common Name, Classification Name, Class & Classification Regulation:

Common Name	*Classification Name*	*Class*	*Classification Regulation*	*Product Code*
Full-Field Laser Perfusion Imager	Probe, Blood-flow, Extravascular	II	870.2120	DPT

Device Description (for detailed description see Section 11)

The PeriCam PSI is a device to perform non-contact imaging of tissue blood perfusion in the microcirculation, for example skin, using Laser Speckle contrast analysis. The full measurement area surface is illuminated with a laser beam resulting in a laser speckle pattern. The pattern is imaged by a CCD camera and image processing of the speckle contrast is used to generate high resolution color code images showing the blood perfusion in the tissue.

Intended Use of the Device

The PeriCam PSI is intended for non-invasive two-dimensional imaging of peripheral tissue blood perfusion. This can be used in a wide range of applications and disciplines including dermatology, wound healing, burns assessment etc.

Summary of technological characteristics of Device and Predicate Device

The new device, PeriCam PSI, illuminates tissue with infra-red laser light. An extended area of the tissue is illuminated using a wide diverging laser beam with homogenous light distribution. The reemitted laser light is imaged using a camera. An interference pattern called speckle pattern is generated in the camera image. The camera image is integrated over a finite exposure time. From the time-integrated images the contrast is calculated as the standard deviation of the intensity-values divided by the mean. For a static measurement object the speckle pattern is constant in time and the contrast over the integrated images will be high. For a dynamic measurement object the speckle pattern will move over time and the contrast will be reduced due to blurring as the speckle pattern is redistributed between the camera-pixels over the integration-time.
Since the measurement laser is invisible a visible laser is also used in the system to indicate the measurement area by generating a visible line surrounding the illuminated area.
The camera images are acquired at video rates in real-time by a PC-software. This PC-software generates colour-coded flow maps of the tissue perfusion from the contrast images.

Comparison to the predicate device K920844, PIM Laser Doppler Perfusion Imager

- **Laser safety**

The predicate device, PIM Laser Doppler Perfusion Imager, employs a collimated narrow laser beam. For each measurement point only a small area is illuminated and measured. By scanning the laser beam using a moving mirror

the entire area is measured sequentially. Since the new device, PeriCam PSI measures the entire area simultaneously a higher total laser radiation is required but since the light is spread out over a larger area the new device is more safe to use. The PeriCam PSI is classified as a Class 1 laser product according to IEC 60825-1:2007, even though it contains two lasers and one is powerful, whereas PIM Laser Doppler Perfusion Imager is classified as a Class 2 laser product according to IEC 60825-1:1993+A1:1997+A2:2001. A Class 1 laser product like PeriCam PSI is considered safe to use also including long-term intra-beam viewing. This is thus safer than the predicate device PIM Laser Doppler Perfusion Imager, which is a Class 2 laser product for which starring into the beam must be avoided.

- **Acquisition rate**

Since the PeriCam PSI is an imaging device the frame-rate of a complete flow-map is up to 100 fps. The predicate device, PIM Laser Doppler Perfusion Imager, is measuring all measurement points sequentially and typical acquisition rate of a complete flow map is minutes for larger areas. The increased frame rate for the new device is a huge advantage enabling several applications that were previously hindered by the slow acquisition rate. Also the fact that the whole image is recorded simultaneously reduces the uncertainty of physiological variations during the recording of one image.

- **Different measurement techniques**

The PeriCam PSI measures blood flow using the LASCA technique whereas the PIM Laser Doppler Perfusion Imager measures blood flow using the laser Doppler technique. The LASCA technique measures the contrast of the time-integrated intensity variations, whereas the laser Doppler technique calculates the frequency content of the time variations of the intensity signal in a single point. These two techniques are different ways of analysing the same fluctuations in the speckle pattern. The integration time of the LASCA technique can be selected so that the response for the LASCA signal and the laser Doppler signal give similar response to flow changes for the relevant measurement objects used in the intended use.

- **Performance Data**

Several comparative studies of the new device and the predicate device have been performed to show the substantial equivalence of the two devices. These include absolute measurements as well relative response to provocations such as heating and occlusion. It can be seen that the response is very similar between the two devices for the intended use of the instruments. It can thus be concluded that the two devices show substantial equivalence.

Conclusion

From the description of the technological characteristics and the performance data, it can be concluded that the PeriCam PSI show substantial equivalence to PIM Laser Doppler Perfusion Imager in terms of the measurement response. The new device is safer than the predicate device since it is defined to laser Class 1 according IEC 60825-1:2007. The new device allows fast acquisition rates for larger measurement areas.

Comparison to the predicate device K063586, moorFLPI Full Field Laser Perfusion Imager

- **Laser safety**

Both instruments employ a wide divergent near infra-red (785 nm) laser beam to illuminate an extended area simultaneously. The new device PeriCam PSI system is assigned to Class 1 according to IEC 60825-1:2007 which is the same class as the moorFLPI Full Field Laser Perfusion Imager which is assigned to Class 1 according to IEC 60825-1:2001. Since both instruments are assigned to laser Class 1 there are no limitations to safe use of the instruments. There is not considered to be any hazard in using the instruments.

- **Measurement efficiency**

The two instruments can measure over approximately the same areas and acquisition rates and are thus considered to be equally efficient in measuring tissue perfusion.

- **Measurement technique**

Both instruments measure tissue perfusion from the contrast reduction of a time-integrated speckle image. Thus the fundamental measurement is based on the same principal for the two instruments, even though the detailed signal processing may differ slightly.

- **Performance Data**

We are not in possession of any moorFLPI Full Field Laser Perfusion Imager so we have not been able to perform any comparative studies.

Conclusion

From the description of the technological characteristics it can be concluded that the PeriCam PSI and the moorFLPI Full Field Laser Perfusion Imager are equally effective in measuring tissue perfusion. The two devices measure using the same fundamental property of reduction of the speckle contrast from blurring caused by moving objects. Thus it can be concluded that the PeriCam PSI show substantial equivalence to the moorFLPI Full Field Laser Perfusion Imager in terms of the measurement effectiveness. The hazard of using the two instruments is identical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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JUL 3 2012

Re: K120884
Trade/Device Name: PeriCam PSI
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular blood flowmeter
Regulatory Class: Class II
Product Code: DPT
Dated: June 11, 2012
Received: June 26, 2012

Dear Ms. Liljevret:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120884

Device Name:
PeriCam PSI

Indications for Use:
The PeriCam PSI is intended for non-invasive two-dimensional imaging of peripheral tissue blood perfusion.

Prescription Use __Yes___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __No___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mkm
(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K120884